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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,460	06/14/2006	Thomas Mann	MTS39USA	6904

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HOWSON & HOWSON LLP
501 OFFICE CENTER DRIVE
SUITE 210
FORT WASHINGTON, PA 19034

EXAMINER	
AFREMOVA, VERA	

ART UNIT	PAPER NUMBER
1657	

NOTIFICATION DATE	DELIVERY MODE
08/07/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@howsonandhowson.com

Office Action Summary	Application No.	Applicant(s)	
	10/596,460	MANN ET AL.	
	Examiner	Art Unit	
	Vera Afremova	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5,6 and 8-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5,6 and 8-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 2, 5, 6 and 8-13 as amended (3/26/2009) are pending and under examination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 5, 6 and 8-13 as amended remain rejected under U.S.C. 103(a) as being unpatentable over US 6,143,555 (Kusunoki et al), US 6,391,577 (Mikkelsen et al) and US 4,528,270 (Matsunaga).

Claims are directed to a method of identifying a microorganism comprising the steps of a) obtaining a test sample of an unknown microorganism; b) adding a mediator or mediator mixture to the test sample in the presence of an effector; c) assessing variation in respiration rate of the microorganism using electrochemical measurements over a pre-determined time period; and d) comparing the variation in the respiration rate of the microorganism with the variation in respiration rates of known microorganisms exposed to the effector, thereby, identifying the unknown microorganism in the test sample. The claimed mediator comprises ferricyanide, dichlorophenol-indophenol (DCIP), ferrocene and ferrocene derivatives, methylene blue, janus green, tris(bipyridyl)iron(III), a quinine (benzoquinone, naphthoquinone, menadione or anthraquinone) or a phenazine (phenazine methosulfate or phenazine ethosulfate) or combinations.

Some claims are further drawn to assessment of respiration rates of microorganisms using electrochemical measurements that are biamperometric or coulometric. Some claims are further drawn to the assessment of respiration rates of microorganisms by the electrochemical measurement of mediator consumption, to the assessment of respiration rates for the pre-determined time period of up to 15 minutes. Some claims are further drawn to the use of microorganisms in an arrested growth state. Some claims are further drawn to the assessment of respiration rates with a plurality of effectors separately. Some claims are further drawn to the use of effector(s) selected from the group consisting of succinate, D-xylose, D-lactose, ornithine, alpha-ketoglutarate, beta-glycerophosphate, D-fructose, sucrose, L-lysine, lactic acid, L-arginine, D-sorbitol, formic acid, L- tryptophan, D-galactose, L-rhamnose, D-arabinose, pyruvic acid, citric acid, malonic acid, D-mannose, beta-cyclodextrin, nitrate and glucose.

US 6,143,555 (Kusunoki et al) teaches a method of identifying an unknown microorganisms by measuring respiration rates of the unknown and known microorganisms in multiple media and comparing the respiration variation rate values between unknown and known microorganisms, thereby, identifying the unknown microorganisms (entire document including abstract). The respiration rates of microorganisms are assessed electrochemically or amperometrically by measuring electric current created by microbial metabolic activities (figures 3-5). The measuring time include interval of 15 minutes (figures 3-5). The generic effectors are generic components of buffer solutions and/or microbiological media (col. 5, lines 55-57) including at least some specific the claim 13 effectors, for example: glucose in grape sugar (col. 5, line 56).

In particular, US 6,143,555 (Kusunoki et al) teaches the use of dissolved oxygen variations as variations in microbial respiration rates and the oxygen in the cited method is a generic mediator or "external chemical oxidant (mediator)" within the meaning of the claimed invention in the light of specification (specification page 6, lines 1-3) and original claims (original claim 3, for example).

Thus, the method US 6,143,555 (Kusunoki et al) is lacking disclosure about the use of specific mediators as required for the claimed method.

However, US 6,391,577 (Mikkelsen et al) teaches method comprising electrochemical detection of microorganisms using mediators such as ferricyanide, dichlorophenol-indophenol (DCIP), ferrocene and ferrocene derivatives, methylene blue, janus green, tris(bipyridyl)iron(III), a quinine (benzoquinone, naphthoquinone, menadione or anthraquinone) or a phenazine (phenazine methosulfate or phenazine ethosulfate), for example: see entire document , abstract and col. 5, lines 5-20. The disclosed effector(s) are selected from the group consisting of succinate, glucose, etc. (col. 7, lines 10-15). Measuring time is 15 minutes (col. 7, lines 15). The method of US 6,391,577 (Mikkelsen et al) is intended for assaying drug cytotoxic effect on microorganisms and it is not intended for identifying unknown microorganisms by comparing electrical current values created by metabolic activities of unknown and known microorganisms.

However, US 4,528,270 (Matsunaga) teaches and/or suggest the use of values of pick current potentials created by metabolic activities of individual microorganisms to distinguish between various types of microorganisms and/or to distinguish between unknown and known microorganisms (entire document including abstract and col. 12, lines 1-15).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use specific mediators of microbial electron transfer disclosed by US 6,391,577 (Mikkelsen et al) in the method of identifying microorganisms based on comparing metabolic respiration rates by electrochemical assessments disclosed by US 6,143,555 (Kusunoki et al) with a reasonable expectation of success in comparing metabolic activity and, thus, identifying microorganisms because pick current potentials created by metabolic activities of individual microorganisms can distinguish between various types of microorganisms as taught and/or suggested by US 4,528,270 (Matsunaga).

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Response to Arguments

Applicant's arguments filed 3/26/2009 have been fully considered but they are not all found persuasive.

Claim rejection under 35 U.S.C. 102(b) as being anticipated by US 6,143,555 (Kusunoki et al) has been withdrawn because the cited method does include the use of specific mediator(s) as required by presently amended claims.

With regard to the claim rejection under 35 USC § 103 applicants argue that there is no suggestion to combine the cited references because they teach various technical details. However, the cited references are in the same field of endeavor (such as measuring microbial

respiration as electron transfer through mediator to electrochemical electrode) and they seek to solve the same problems as the instant application and claims (such as detecting, identifying, classifying microorganisms and/or microbial respiratory response depending on microbial culture conditions), and one of skill in the art is free to select components available in the prior art, *In re* Winslow, 151 USPQ 48 (CCPA, 1966).

With regard to US 6,143,555 (Kusunoki et al) applicants argue that it does not teach or suggest measurement of variation in respiration rate and utility of such measurement for identification of unknown microorganisms (response page 5, par. 3). However, the cited document clearly states that "signal resulting from multiple respiration rate determinations is compared with known values to identify the microorganisms", for example: see abstract. Thus, the cited document teaches and/or suggests measurement of the variation in respiration rate as applied to identification of microorganisms. The claimed method is generic with regard to measurement of variation in respiration rate and/or it does not point out what is intended by "assessing variation in respiration rate" as argued. Applicants appear to argue the use of "different culture conditions" (response page 6, last par.). But the claimed method does not encompass the use of "different culture conditions" as argued and it is not clear what they might be as claimed, as disclosed and as argued.

With regard to US 6,143,555 (Kusunoki et al) applicants also argue that the cited method is based on measurements of dissolved oxygen and, thus, it is solely applicable not applicable to anaerobic microbes (response page 6, par. 4 and page 7, par. 2). Yet, the claimed method is genetic and does not explicitly recite exclusion of aerobic cultures.

With regard to US 6,143,555 (Kusunoki et al) and with regard to the claim rejection as a whole applicants further argue that the prior art methods require *a priori* knowledge of what may be present in the test sample (response page 5, par. 3; page 7, par. 1 and page 8, last par.). This argument does not have any persuasive grounds because any microbial testing or assay method including the applicants' method is relied upon on a prior knowledge of microbial characteristics and possibility of their manifestation in the testing sample.

With regard to US 6,391,577 (Mikkelsen et al) Applicants argue that the cited method is directed to screening drug testing and does not contemplate identification of unknown microorganisms. However, microbial sensitivity to drugs, antibiotics and/or other chemicals is a microbial characterization used for classification and identification of microorganisms. Thus, the methods as disclosed and as presently claimed are obvious variants.

With regard to US 4,528,270 (Matsunaga) Applicants appear to argue that the cited method is based on a different mechanism of action. However, US 4,528,270 (Matsunaga) is relied upon for the teaching that electron transfer or current created by metabolic activities of individual microorganisms can be used to distinguish between various types of microorganisms and/or to distinguish between unknown and known microorganisms (entire document including abstract and col. 12, lines 1-15). Even if the cited US 4,528,270 (Matsunaga) does not disclose same mediators of electron transfer as claimed and/or as argued, the other cited reference US 6,391,577 (Mikkelsen et al) explicitly teaches identical mediators as required by the instant claims as intended for microbial characterization and classification. Thus, the cited methods as disclosed and as presently claimed are obvious variants.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

July 30, 2009

/Vera Afremova/
Primary Examiner, Art Unit 1657